

## REMARKS

### Status of the Claims

In the Amendment Pursuant to 37 C.F.R. §1.114 filed by Applicants on December 10, 2007, independent claims 5, 13, 19, and 42 were amended as follows:

(1) to remove the limitation “said composition being free of glycerol and polyethylene glycol polymers,” **and**

(2) to include the limitation that the compositions are prepared using a method “**consisting of**” the steps recited in these claims.

As noted in that Amendment, support for limiting the method of preparation to the recited steps resides throughout the specification, for example, in the Experimental section. No new matter was added by way of claim amendment.

The Amendment filed December 10, 2007, accompanied a Request for Continued Examination under 37 C.F.R. §1.114, and the appropriate fee. According to the most recent non-final Office Action issued by the Examiner on February 15, 2008, Applicants’ Amendment filed December 10, 2007 was entered, and no new matter rejections were raised over the claim amendments presented therein. Accordingly, all of the pending claims include the limitation that the compositions are prepared using a method “**consisting of**” the steps recited in these claims.

As a result of the removal of the limitation “said composition being free of glycerol and polyethylene glycol polymers,” the previous rejection of claims 5-9, 13-17, 19, 20, 26-43, and 45-49 under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement (new matter), has now been withdrawn. See the current non-final Office Action mailed February 15, 2008, at page 2, item 4.

Claims 5-9, 13-17, 19, 20, 26-43, and 45-49 are pending in the application. Reexamination and reconsideration of the pending claims are respectfully requested in view of the following remarks. The Examiner’s comments in the Office Action are addressed below in the order set forth therein.

The Rejection of the Claims Under 35 U.S.C. §103 Should Be Withdrawn

In view of the removal of the limitation “said composition being free of glycerol and polyethylene glycol polymers” from the independent claims, the Examiner has reapplied the rejection of claims 5-9, 13-17, 19, 20, 26-43, and 45-49 under 35 U.S.C. §103 as being obvious over Dorin *et al.* (U.S. Patent No. 5,814,485; hereinafter the “485 patent”) in view of Hershenson *et al.* (U.S. Patent No. 5,004,605; hereinafter the “605 patent”) and further in view of the Merck Index (1989) (hereinafter “Merck”). Applicants respectfully submit that this rejection has been reapplied in error.

The Examiner has previously acknowledged that the '605 patent “**requires the use of a stabilizer.**” See the Office Action mailed April 13, 2006, at page 5, last paragraph, lines 4-5. Furthermore, when Applicants’ claims were amended to include the limitation that the presently claimed compositions are “free of glycerol and polyethylene glycol polymers,” this §103 rejection over the combined teachings of the '485 patent, the '605 patent, and Merck was **withdrawn**. See the Office Action dated November 27, 2006, at page 2, item 4.

When the Examiner withdrew the §103 rejection over the combined teachings of the '485 patent, the '605 patent, and Merck, he stated that he would reinstate this rejection if Applicants amended the claims to remove the limitation “said composition being free of glycerol and polyethylene glycol polymers,” in order to address the new matter rejection under Section 112 that was issued in the Office Action dated November 27, 2006.

In the present Office Action, the Examiner states that this §103 rejection is reapplied because Applicants have amended the claims to remove the phrase “said composition being free of glycerol and polyethylene glycol polymers.” However, in so doing, the Examiner has ignored the second amendment that was made to each of the independent claims, and thus to all of the pending claims. This amendment requires that the method used to prepare the compositions recited in each and every one of these claims “**consists of**” the steps recited in the respective claims. As the method steps fail to recite the addition of glycerol and polyethylene glycol polymers, the compositions of the claimed invention necessarily are free of glycerol and polyethylene glycol polymers.

Appl. No.: 10/035,420  
Amendment Dated July 15, 2008  
Response to Office Action of February 15, 2008

Accordingly, by the Examiner's own admission and previous withdrawal of this §103 rejection, this §103 rejection of the claims never should have been reapplied following entry of the claim amendments presented in Applicants' Amendment filed December 10, 2007.

As the pending claims recite methods and compositions not taught or suggested by the '485 patent when combined with the teachings of the '605 patent and Merck, Applicants respectfully submit that this §103 rejection should be withdrawn.

#### The Non-Statutory Double-Patenting Rejection of the Claims Should Be Withdrawn

Claims 5-9, 13-17, 19, 20, 26-28, 31-33, 35-40, 42, 43, and 45-48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8, 9, 31-35, 61-63, 68, 69, 70, and 75-77 of U.S. Patent No. 6,887,462.

A terminal disclaimer in compliance with 37 C.F.R. §1.321(c) is filed concurrently herewith. In view of this submission, Applicants respectfully submit that this rejection is now overcome.

#### Information Disclosure Statement

Applicants take this opportunity to bring to the Examiner's attention commonly owned U.S. Patent No. 7,371,373, issued May 13, 2008, and commonly owned U.S. Patent No. 7,399,463, scheduled for issuance on July 15, 2008. The Examiner is respectfully requested to make his consideration of these documents of record in this case.

Terminal disclaimers in compliance with 37 C.F.R. §1.321(b) are filed concurrently herewith with respect to these two issued patents. Entry of these terminal disclaimers into the record of the present application is respectfully requested.

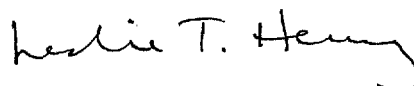
### **CONCLUSION**

In view of the foregoing remarks and submission of the terminal disclaimers noted above, Applicants respectfully submit that the rejection of the pending claims under 35 U.S.C. §103 and the obviousness-type double-patenting rejection are overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned attorney.

Appl. No.: 10/035,420  
Amendment Dated July 15, 2008  
Response to Office Action of February 15, 2008

It is not believed that extensions of time or fees are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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